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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/603,129	06/24/2003	David J. Schuessler	33915-03420	9875
27171	7590	05/03/2006		
MILBANK, TWEED, HADLEY & MCCLOY 1 CHASE MANHATTAN PLAZA NEW YORK, NY 10005-1413				
			EXAMINER MIGGINS, MICHAEL C	
			ART UNIT 1772	PAPER NUMBER

DATE MAILED: 05/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/603,129

Applicant(s)

SHUESSLER

Examiner

Michael C. Miggins

Art Unit

1772

— The MAILING DATE of this communication appears on the cover sheet with the correspondence address —

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 February 2006.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 23-44 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 23-44 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

REJECTIONS WITHDRAWN

1. There are no rejections withdrawn.

REJECTIONS REPEATED

2. All of the 102 and 103 rejections set forth in the non-final rejection of 11/3/05, pages 2-5, paragraphs 3-8. Applicant has added the limitation "obtained by the process of rotational molding" to claim 23. However, said limitation is a process limitation in a product claim and process limitations are not germane to the patentability of a product in a product claim (MPEP 2113). There is no claimed structural difference between the claim and the prior art therefore the claim is still anticipated as written.

NEW REJECTIONS

3. There are no new rejections.

ANSWERS TO APPLICANT'S ARGUMENTS

4. Applicant's arguments of 2/16/06 have been carefully considered but are deemed unpersuasive.

Applicant has added the limitation "obtained by the process of rotational molding" to claim 23. However, said limitation is a process limitation in a product claim and process limitations are not germane to the patentability of a product in a product claim

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(MPEP 2113). There is no claimed structural difference between the claim and the prior art therefore the claim is still anticipated as written.

Applicant has argued that the references do not disclose a removable liner. However, it is well known in the art to provide a releasable liner for an article during packaging, transportation or storage.

Applicant has argued that the references do not disclose applicant's claimed thickness recited in claim 27. However, thickness is a well known result effective variable and finding the workable or optimum working range for a result effective variable is obvious (MPEP 2144) and it would have been obvious to have provided applicant's claimed thickness in order to add protection to the article and/or lower production costs by using less material.

Applicant has argued that the prior art does not teach a patchless shell for a medical device obtained by rotational molding. However, rotational molding is a process limitation in a product claim and process limitations are not germane to the patentability of a product in a product claim (MPEP 2113).

Conclusion

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not

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mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

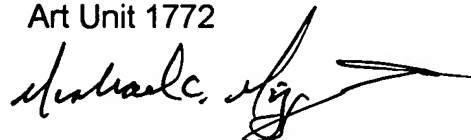
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Miggins whose telephone number is 571-272-1494. The examiner can normally be reached on 1:00-10:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Harold Y. Pyon can be reached on 571-272-1498. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MCM
April 28, 2006

Michael C. Miggins
Primary Examiner
Art Unit 1772

A handwritten signature in black ink, appearing to read "Michael C. Miggins", with a long horizontal flourish extending to the right.